

CERTIFICATE OF MAILING 37 C.F.R. 1.8(a)

hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, Alexandria, VA 22313 on the date indicated below.

Date

October 2005

Shirley Gruen

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:)	
Lewis, <i>et al.</i>)	Confirmation No. 9722
)	
Serial No.: 09/812,704)	Examiner: Christopher Gilligan
)	
Filed: March 19, 2001)	Group Art Unit: 3626
)	
For: METHODS AND SYSTEMS FOR)	Attorney Docket No. 044258.000003
HEALTHCARE PRACTICE)	
MANAGEMENT)	

SECOND DECLARATION OF ARMANDO FUENTES
UNDER 37 CFR 1.132

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

I, Armando Fuentes, state the following:

1. I have a Bachelor of Science in Biology degree (1978), a Doctorate of Medicine degree (1982), Master of Business Administration degree (1990) and I have been a practicing physician for over twenty-three years. I am a member of the American College of Physician Executives, a certified member of the American Board of Obstetrics and Gynecology in both Obstetrics and Gynecology and Maternal Fetal Medicine, a Diplomate of the National Board of Medical Examiners and a member of numerous other professional societies. I have co-authored and published over twenty scientific articles or abstracts and have participated in the presentation of over twenty-five lectures. Although most of these presentations or lectures have been obstetric related, I have participated in presentations on management strategies and practice management. My business experience includes: current Medical Director for Matria Healthcare, which involves assessing and developing various processes of disease management. Past

experience includes: physician owner of a fetal diagnostic center; President and Chief Executive Officer of Medvid, Inc., in which capacity I developed and owned PC remote ultrasound equipment, engaged in product development with hardware and software database applications for remote interpretation of fetal ultrasounds, and was employed as a Quality Assurance and Risk Management Consultant who provided direction to medical practices and hospital medical staff to develop best practice guidelines to reduce liability. I have been a hospital department chair and have held several academic positions. Currently, I am licensed to practice medicine in Florida and New York.

2. I am familiar with and understand the subject matter of the above-identified patent application. I have studied the application and the amendments to the application and the cited patent documents of record in the application.

3. I have read and studied U.S. Patent No. 6,370,511 (hereinafter "Dang") attached at Exhibit A; I have read the article *New Compensation Model Improves Physician Productivity* authored by Alexandra Davis and C. Hardy Thompson and published in Healthcare Financial Management, July 1999, 53, 7, pg. 46 (hereinafter "Davis"), attached at Exhibit B, which outlines the development of a new compensation plan that bases pay on the application of a collection rate percentage to each physician's gross fee-for-service billings; and lastly, I have read and studied U.S. Patent No. 6,012,035 (hereinafter "Freeman") attached as Exhibit C. I also have read and studied the other patent documents cited in the U. S. Patent and Trademark Office in this matter as listed in the attached Exhibit D.

4. In my opinion, the present claimed invention, Claims 1-37, 39-46 and 51-56, advantageously provides a system and method for managing a healthcare practice which enhances profitability of the healthcare practice and is unique and operationally quite different than other systems and methods I have seen before and as set forth in the patent documents at Exhibits A, B and C. It is my opinion that the claimed invention, Claims 1-37, 39-46 and 51-56 would not be obvious to one of ordinary skill in the art at the time this application was filed. It is also my opinion that one skilled in the art would lack motivation to combine Dang and Davis or Dang, Davis, and Freeman to somehow arrive at the claimed invention.

5. For example, in my opinion, the present claimed invention transforms physician's cost management behavior to enhance profitability of healthcare practices and insurance

networks by identifying physicians that are not profitable because of cost management behavior and provides a method and system of intervention to change the management behavior of the physician. Further, the establishment of cost norms with predetermined reimbursement amounts would not be an obvious development in view of the patent documents cited at Exhibits A, B and C, individually or in combination.

6. I believe that the present claimed invention as set forth in Claims 1-37, 39-46, and 51-56 offers a unique and viable solution for identifying, measuring, and controlling costs and cost-effectiveness of care. The present claimed invention will and does provide an important contribution to healthcare management.

7. Also, for example, as reasons for lack of motivation to combine these patent documents and for lack of obviousness of the claimed invention, for example, management can be defined in three areas: to administer, control and cope. The Freeman and Dang patents focus on “administration“ (See Freeman, Col. 3, lines 1-9 and Dang, Col. 1, lines 43-54); whereas, the present claimed invention focuses on cost “control” (See present application, e.g. Claim 1, lines 9-18, Claim 8, lines 1-7, Claim 10, lines 1-9, Claim 13, lines 9-19, Claim 20, lines 1-7 and, Claim 21, lines 1 – 9). When effecting a change program, the process must address: (1) what to change, (2) what to change to, and (3) how to cause or affect the change. Freeman and Dang (See Freeman, Col. 2, lines 45-53 and Dang, Col. 1, lines 26-31) show which cooperative entity is responsible for the costs, as does the present application (See present application, e.g. Claim 15, lines 1 – 6). Dang (See Dang, Col. 10, line 67 - Col. 11, line 18) quantifies the costs and compares them to others on an adjusted basis, while the present application takes a related approach for comparison (See present application, e.g. Claim 15, lines 1 – 6). The present claimed invention, however, is critical because in cost control it shows how to cause or affect the change (See present application, e.g. Claim 13, lines 15 – 19; Claim 17, lines 1 – 7; Claim 19, lines 1 – 6; and Claim 21, lines 1 – 2). Freeman and Dang, on the other hand, do not offer a change process or solution for controlling costs (expenses), individually or in combination with Davis (See Davis, Para. 17, line 1 – 2). The present claimed invention offers a solution for measuring, controlling costs and controlling the cost effectiveness of care. Unlike Lewis, nowhere in Freeman, Dang, or Davis are standards of care identified (See present application, e.g. Claim 17, line 1 – 7), quantified (See present application, e.g. Claim 14, line 1 – 6), and used as a measurement standard for physician performance (See present application, e.g. Claim 15, line 1 – 6). As such, it is difficult to understand how one skilled in the art would have motivation

to combine the patents, and it is my understanding that the result still would not be the present claimed invention as set forth in Claims 1-37, 39-46 and 51-56.

8. Further, for example, as additional reasons, the Davis article (See Davis, Para. 17, line 1 – 2) describes revenue; the present claimed invention describes expenses (See present application, e.g. Claim 24, line 1 – 6). Davis (See Davis, Para. 21, line 1 – Para. 22, line 11) requires physicians to increase their gross billings to maximize their compensation. Conversely, Lewis (See present application, e.g. Claim 13, line 1 – 5 and Claim 17, line 1 – 7) compels physicians to follow researched standards of care to only incur necessary ancillary medical costs as a means to increase practice or insurer profitability. Lewis supports this action with several methods of physician behavior modification (See present application, e.g. Claim 13, line 15 – 19; Claim 17, line 1 – 7; Claim 19, line 1 – 6; and Claim 21, line 1 – 2). However, Davis' (See Davis, Para. 23, line 4 – 7) behavior modification is only to induce physicians to increase billing revenues through marketing to increase the number of patients, which is rewarded under a full revenue recognition capitation model (See Davis, Para. 20, line 7 – 9), as well as to increase the prescription of ancillary testing services to maximize billings per patient. Davis does not focus on measuring or controlling costs. Rather, Davis (See Davis, Para. 4, line 4 – Para. 5, line 12) deals strictly with physicians on the payroll of a specific healthcare organization and offers a change process or measurement system which does not address clinically appropriate steps to increase their measures. Increased productivity does not necessarily increase the quality of care or control costs (See Davis, Para. 17, line 1 – 2); however, it most assuredly will increase the workload of the physician. The present claimed invention employs physician behavior modification, for example, in the areas of increased utilization of step therapies, greater training in clinical prescribing guidelines, and tools to counsel patients on the perils of starting new treatment with last-line, high cost drugs, all of which are cost control measures (See present application, e.g. Claim 17, line 1 – 7).

9. Additionally, as described in the background section of the present patent application, as well-known in our society, as discussed abundantly in literature, as observed by me, and based on my experience, there has been a long felt need for a solution to the problem identified and addressed so elegantly by the inventors in the present application, especially in terms of identifying, measuring and controlling costs and controlling the cost effectiveness of care. Notably, as described in paragraphs 6-8 above, none of these patent documents recognize or address a change process or solution for controlling costs, and thus further confirms and


treatment with last-line, high cost drugs, all of which are cost control measures (See present application, e.g. Claim 17, line 1 – 7).

9. Additionally, as described in the background section of the present patent application, as well-known in our society, as discussed abundantly in literature, as observed by me, and based on my experience, there has been a long felt need for a solution to the problem identified and addressed so elegantly by the inventors in the present application, especially in terms of identifying, measuring and controlling costs and controlling the cost effectiveness of care. Notably, as described in paragraphs 6-8 above, none of these patent documents recognize or address a change process or solution for controlling costs, and thus further confirms and indicates to me that this long felt need was not being met prior to Applicant's present application, including Claims 1-37, 39-46, and 51-56.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Sec. 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the publication or any patent issued thereon.

FURTHER DECLARANT SAYETH NOT.

10/21/05
Date


By: Armando Fuentes
Address: 2550 Westminster Terrace
Oviedo, Florida 32765-7501

indicates to me that this long felt need was not being met prior to Applicant's present application, including Claims 1-37, 39-46, and 51-56.

10. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Sec. 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the publication or any patent issued thereon.

FURTHER DECLARANT SAYETH NOT.

Date

By: Armando Fuentes
Address: 2550 Westminster Terrace
Oviedo, Florida 32765-7501